UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IN RE: BAYER CORP COMBINATION ASPIRIN PRODUCTS MARKETING AND SALES PRACTICES LITIGATION	09-md-2023 (BMC) (JMA)
NINA GOLDBERG, WILLIAM BLANK, ROBERT NOSBISCH, DOUGLAS VINSON, and LYNNE NOSBISCH, individually and on behalf of all others similarly situated, Plaintiffs, -against- BAYER HEALTHCARE LLC, Defendant.	

COGAN, District Judge

PLAINTIFFS' RESPONSE IN OPPOSITION TO BAYER HEALTHCARE LLC'S MOTION TO DISMISS THE MASTER COMPLAINT

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I. INTRODUCTION

Bayer Healthcare LLC ("Bayer") sold and marketed to the Class two over-the-counter ("OTC") pharmaceutical products, "BAYER WOMEN'S Low Dose Aspirin + CALCIUM" ("Bayer Calcium") and "BAYER ASPIRIN With HEART ADVANTAGE" ("Heart Advantage") (collectively the "Products"), as combination OTC drugs and dietary supplements. To push its Products, Bayer's marketing included misrepresentations that: (i) the Products had Food and Drug Administration ("FDA") approval (when they did not); (ii) the Products were appropriate for daily and long-term use (which they are not); and (iii) Heart Advantage "lowers cholesterol" and Bayer Calcium "fights osteoporosis" (when they do not). Absent these misrepresentations, Plaintiffs and the Class would not have purchased the Products. Because the Master Complaint[1] contains "'well-pleaded factual allegations[, the] court should assume their veracity…,'" and determine they plausibly give rise to an entitlement to relief. *Stair v. Calhoun*, 2009 U.S. Dist. LEXIS 94289, at *5 (E.D.N.Y. Oct. 8, 2009) (quoting *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949-50 (2009)). Accordingly, Defendant's Motion to Dismiss should be denied.

II. SUMMARY OF FACTUAL ALLEGATIONS

A. Bayer Misrepresented the Approval, Safety and Efficacy of the Products in Its Marketing to Plaintiffs and the Class

1. Bayer misrepresented the approval of the Products

Bayer misrepresented whether the Products were FDA approved. ¶¶ 5, 26, 27, 39, 41, 43, 65. Since the late 1800s, Bayer has been associated with aspirin. ¶¶ 16, 56-57. Consequently consumers were led to believe that the Products at bar in this lawsuit were part of the family of aspirin products for which Bayer had received regulatory approval to sell for their marketed

[1] The Master Complaint is hereinafter referred to as the "Complaint" and cited to as "¶ ___."

purposes. ¶¶ 5, 26, 27, 39, 41-43, 65. However, Bayer had not received FDA approval for Bayer Calcium and Bayer Heart Advantage.[2]

The FDA has previously advised consumers that combining dietary supplements and OTC drug ingredients should not be held out as FDA approved, stating:

> These types of combination products raise a number of significant public health and policy issues. For example, the addition of a new ingredient to a legally marketed drug product could affect the safety and efficacy of the drug component. In addition, consumers may be confused about the degree of scrutiny FDA gives such combination products. Consumers may believe that both components have been subjected to the more stringent drug regulatory requirements when, in fact, only the drug component may have been reviewed by the agency for safety and effectiveness.

¶ 26. Despite the fact that the FDA specifically recognized that the sale of products like the Combination Aspirins without FDA approval would serve to "confuse" consumers, Bayer marketed and sold the Products anyway. ¶ 27.

In fact, on its website, Bayer provides further misleading statements designed to confuse consumers that Bayer Heart Advantage – and specifically the phytosterols in combination with aspirin – has received regulatory approval. ¶ 65. For example, Bayer states:

> Phytosterols, a natural plant-based ingredient, have been proven to lower cholesterol. Phytosterols reduce a person's LDL cholesterol level by helping block the absorption of cholesterol from the digestive tract. The FDA has recognized the use of phytosterols (at least 800mg a day in divided doses) as part of a low-fat diet to cut the risk of heart disease.

Id.

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[2] Because the Products were "intended to affect the structure or function of the body," they were drugs for purposes of 21 U.S.C. § 321(g)(1). ¶¶ 20, 45, 77. Also, because the combination of ingredients in Bayer Calcium (aspirin and calcium carbonate) and Heart Advantage (aspirin and phytosterols) had not yet been recognized as safe and effective for their intended uses, they were "new drugs" as defined by 21 U.S.C. § 321(p)(1). ¶¶ 46, 78. A pharmaceutical manufacturer cannot manufacture a new drug and distribute it to the public without first seeking pre-market approval from the FDA under the Federal Food, Drug, and Cosmetic Act ("FDCA"). *Wyeth v. Levine*, ___ U.S. ___, 129 S. Ct. 1187, 1195 (2009). *See* ¶ 19. Despite Bayer's awareness of the requirements of the FDCA, Bayer chose to distribute the Products to the public and market them as safe and effective for certain uses even though they had not been approved for such uses. ¶¶ 1, 25.

2. Bayer misrepresented the safety of the Products

Bayer also misrepresented the safety of the Products. ¶ 3. Taking aspirin long-term should be under a doctor's supervision, as the medicine is meant for short-term use. ¶ 4. The long-term use of aspirin can cause serious side effects like gastrointestinal bleeding. ¶ 4. Thus, Defendant misrepresented the safety of the Products when encouraging their daily and long-term use. *See, e.g.* ¶ 61.

Bayer's labeling of the two drugs created confusion and sent mixed messages to the public because Bayer disseminated inadequate directions on how to use the drugs. ¶¶ 3, 48-51, 69. Bayer directed that the aspirin component of each drug be taken pursuant to a daily regimen (¶¶ 36, 40, 59), while at the same time it directed that the calcium carbonate component of Bayer Calcium be taken up to four times per day (¶ 37[3]) and the phytosterols component of Bayer Heart Advantage be taken twice a day (¶¶ 64, 67[4]). Thus, persons wanting to reap the benefits of the "dietary supplement" component of either drug would have to take the drug more than once a day, which would be in contradiction to the FDA recommendation that aspirin be taken according to a daily regimen. ¶¶ 37, 64, 67.

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[3] The package label states: "Provides 300mg of Calcium Which Helps Strengthen Bones To Help Fight Osteoporosis." ¶ 37. The label also states:

> Menopausal women and women with a family history of the disease are groups at risk for developing osteoporosis. Adequate calcium intake throughout life, along with a healthy diet and regular exercise, builds and maintains good bone health and may reduce the risk of osteoporosis. While adequate calcium intake is important, daily intakes above 2,000 mg may not provide additional benefits.

¶ 37. The label prominently features a glass of milk in close proximity to these statements and to the name, "Bayer Women's Low Dose Aspirin + CALCIUM," implying that Bayer Calcium is a source of dietary calcium. ¶ 38.

[4] For example, the carton label states: "DIETARY SUPPLEMENTS OR FOOD CONTAINING AT LEAST 400MG PER SERVING OF FREE PHYTOSTEROLS, EATEN TWICE A DAY WITH MEALS FOR A DAILY TOTAL INTAKE OF AT LEAST 800 MG, AS PART OF A DIET LOW IN SATURATED FAT AND CHOLESTEROL, MAY REDUCE THE RISK OF HEART DISEASE BY LOWERING BLOOD CHOLESTEROL. EACH BAYER HEART ADVANTAGE DUO-CAP CONTAINS 400MG OF FREE PHYTOSTEROLS." ¶ 64 (all caps in original).

3. Bayer misrepresented the efficacy of the Products

In addition, Bayer misrepresented the efficacy of the Products. For example, in a graphic depicting Bayer's aspirin products, including Heart Advantage, Bayer's website states "[n]o other over-the-counter pain reliever has been around as long or has been researched as extensively as aspirin, nor has any been proven to be more effective." ¶ 58. Indeed, Bayer describes aspirin as a "wonder drug" and a "miracle drug that works wonders." *Id.* Bayer even uses the domain name www.wonderdrug.com to promote its aspirin products, including Bayer Heart Advantage. *Id.*

To provide any putative benefit, the dosage of phytosterols necessary to be consumed equals 2 tablets of Bayer Heart Advantage. ¶ 67. By contrast, a daily aspirin regimen consists of a single 81mg tablet. Thus, a person cannot simultaneously ingest the recommended dose of aspirin while obtaining any purported cholesterol lowering effects of phytosterols. ¶ 67.

In addition, Bayer misrepresented the efficacy of Bayer Calcium by relying on statements relating to a separate product. Statements on the labeling enclosed within the carton state facts pertaining to the prevention of cardiovascular disease that are standard to Bayer Aspirin. *See, e.g.*, ¶ 41 ("It has been proven that regular aspirin use can prevent 1 out of 4 heart attacks among patients with a previous event"). However, Bayer Calcium was never approved by the FDA unlike Bayer Aspirin. Therefore, the statements on the labeling enclosed within the carton misrepresent the fact that these statements pertain to the FDA-approved Bayer Aspirin and not to the unapproved Bayer Calcium or its efficacy. ¶ 42.

B. Plaintiffs Were Actually Deceived

Plaintiffs are residents and citizens of New Jersey (William Blank), Illinois (Robert and Lynn Nosbisch), California (Douglas Vinson), and New York (Nina Goldberg). ¶¶ 9-13. Based on Bayer's representations, Plaintiffs purchased either Heart Advantage or Bayer Calcium. ¶ 9

(Ms. Goldberg purchased Heart Advantage "[u]pon seeing Bayer Heart Advantage's 'cardio protective' claims at her local CVS"); ¶ 10 (Mr. Blank purchased Heart Advantage "[a]fter seeing advertisements representing that Bayer Aspirin with Heart Advantage could help lower cholesterol levels...."); ¶ 11 (Mr. Nosbisch purchased Heart Advantage "based on representations on the package that the product could help lower cholesterol levels."); ¶ 12 (Mr. Vinson purchased Heart Advantage "[a]fter seeing advertisements representing that Bayer Aspirin with Heart Advantage could help lower cholesterol levels"); ¶¶ 11, 13 (Mrs. Nosbisch purchased Bayer Calcium based on the package representations seen at the same time as her husband's purchase of Heart Advantage). Plaintiffs believed that Bayer's sale of the Products was the result of the FDA-approval process. ¶¶ 9-13. Absent the deception, Plaintiffs would not have purchased the Products. ¶¶ 9-13.

Bayer's misrepresentations and omissions regarding the Products were brought to the public's attention as a result of the FDA's warning letters to Bayer dated October 27, 2008. ¶¶ 44, 76. Prior to the FDA's letters, Plaintiffs did not know, nor should they or could they have known, that the Products were not FDA approved, nor that they had not been found to be safe or effective for the treatment of heart disease, osteoporosis and/or lowering cholesterol.

C. Plaintiffs and the Class Were Damaged

Bayer has been marketing Heart Advantage since early 2008 and Bayer Calcium since 2002. ¶ 6. The Products should never have been sold and should not have been marketed in the manner in which they were. ¶ 6. Plaintiffs and the Class suffered economic damages by purchasing the Products and are entitled to a full refund for their purchases. ¶¶ 6, 84.

III. ARGUMENT

A. Plaintiffs' Claims Meet all Threshold Requirements

In Section II of their motion papers, Defendants blur the lines between three distinct arguments: (1) whether Plaintiffs adequately state a claim; (2) whether the choice of law determination should be made at this stage; and (3) whether Plaintiffs have Article III standing versus whether they have standing to represent consumers that reside in other states.

1. Plaintiffs have satisfied the applicable pleading requirements

a) The Complaint states claims that are plausible

Bayer argues that Plaintiffs' claims fail because they are implausible. See Def. Br., at 2. But Defendant's implausibility argument rests, in part, on 'facts' that are contrary to the facts alleged in the Complaint.[5] The legal standard set forth in *Twombly* and in *Iqbal* amply support Plaintiffs' claims here. The Complaint is replete with "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, __ U.S. __, 129 S. Ct. 1937, 1949 (2009). *See also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (the complaint must "give the defendant fair notice of what the ... claim is and the grounds upon which it rests."). Rather than apply the facts as alleged, Bayer supplies its own 'facts' and then applies the legal standard to the 'facts' as it casts them. However, even after *Twombly* and *Iqbal*, this it cannot do.[6]

b) Plaintiffs' claims are governed by and adequately pleaded under Rule 8(a)

Federal Rule of Civil Procedure 8(a)(2) requires Plaintiffs to provide only "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P.

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[5] *See* Plaintiffs' Response in Opposition to Defendant's Request for Judicial Notice.

[6] Curiously, Defendants have Answered at least one other complaint in this litigation which arguably was not as well-plead as the Master Complaint. *See Nina Goldberg, et al. v. Bayer Healthcare Corp., et al.*, Case No: 08-CV-4623 (BMC), Doc # 19.

8(a)(2). "Rule 8(a)'s simplified pleading standard applies to all civil actions, with limited exceptions." *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 513 (2002).

Citing *Swierkiewicz,* several courts have held that this simplified standard applies to claims for violation of consumer protection statutes and unjust enrichment. *See, e.g., Pelman v. McDonald's Corp.*, 396 F.3d 508, 511 (2d Cir. 2005) ("an action under § 349 [of the New York General Business Law] is not subject to the pleading-with-particularity requirements of rule 9(b), Fed. R. Civ. P., but need only meet the bare-bones notice-pleading requirements of rule 8(a), Fed. R. Civ. P."); *GE Capital Corp. v. Posey*, 415 F.3d 391, 396-97 (5th Cir. 2005) ("Other than in the situations *expressly* enumerated in Rule 9(b), *e.g.*, allegations of *actual* fraud, plaintiffs must satisfy *only* the minimal requirements of Rule 8(a).") (emphasis added); *Allstate Ins. Co. v. Rozenberg*, 590 F. Supp. 2d 384, 395 (E.D.N.Y. 2008) (same); *Lawson v. Affirmative Equities Co., L.P.*, 341 F. Supp. 2d 51, 67 n.25 (D. Mass. 2004) (same). Indeed, *Swierkiewicz* "sounded the death knell for the imposition of a heightened pleading standard except in cases in which either a federal statute or specific Civil Rule requires that result." *Lawson*, 341 F. Supp. 2d at 67 n.25 (quoting *Educadores Puertorriqueños en Acción v. Hernández*, 367 F.3d 61, 66 (1st Cir. 2004)).

c) Even if Rule 9(b) applies, Plaintiffs have met Rule 9(b)'s heightened pleading requirements

Even if Plaintiffs are required to plead their consumer protection claims under Rule 9(b), their allegations are sufficient to meet this pleading requirement. Rule 9(b) requires a plaintiff to plead with particularity "the circumstances constituting the fraud or mistake." Fed. R. Civ. P. 9(b). However, Rule 9(b) should be applied sensibly so as not to allow "defrauders" to hide behind procedure. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997). "Indeed, under rule 9(b), even for allegations of fraud, not every alleged

misrepresentation need appear in the pleadings." *Posey*, 415 F.3d at 397 n.7. Since the Complaint contains factually-based paragraphs that detail the conduct providing the basis for the relief requested, *see* ¶¶ 1-6, 9-13, 19-84, the Motion should be denied.[7]

2. The choice of law decision should be deferred until class certification at which time Plaintiffs will demonstrate that New Jersey law should apply nationwide

It is premature for the Court to decide on a motion to dismiss what substantive law should be applied to the facts of this case. The choice of law analysis in a class action is properly undertaken in the context of the class certification predominance analysis under Rule 23(b)(3). *See, e.g., Huber v. Taylor*, 469 F.3d 67, 73-74 (3d Cir. 2006) (conducting extensive choice of law analysis in review of class certification decision); *Spence v. Glock GES, m.b.H*, 227 F.3d 308, 311 (5th Cir. 2000) (finding that the threshold question in reviewing a class certification decision is "whether the district court conducted a proper choice of law analysis"). *See also In re Vioxx Prods. Liab. Litig.*, 239 F.R.D. 450 (E.D. La. 2006); *In re Relafen Antitrust Litig.*, 221 F.R.D. 260, 275 (D. Mass. 2004); *In re Baycol Prods. Liab. Litig.*, 218 F.R.D. 197 (D. Minn. 2003); *In re Warfarin Sodium Antitrust Litig.*, 212 F.R.D. 231 (D. Del. 2002), *aff'd*, 391 F.3d 516 (3d Cir. 2004).

It makes intuitive sense to defer this crucial decision until the litigation has matured to the point where a motion for class certification is filed.[8] The question here is not whether the

[7] Further, even if Plaintiffs have not adequately alleged their claims with sufficient particularity, "[t]he proper remedy for failure to plead fraud with particularity is not dismissal of the claims or striking of the pleading, but allowance of 'a motion for a more definite statement, an amendment under Rule 15, or the use of the discovery procedures.'" *Molex Inc. v. Wyler*, 365 F. Supp. 2d 901, 912 (N.D. Ill. 2005) (citing Charles A. Wright & Arthur R. Miller, FEDERAL PRACTICE AND PROCEDURE: CIVIL 3D § 1291 at 16 (2004)).

[8] The *Rios* court explained:

> As noted previously, the Court will be required to conduct a rigorous analysis on the conflicts of law at the *certification* stage after further discovery, and may ultimately conclude that Plaintiffs cannot meet the commonality requirement. *See In re St. Jude Medical Inc.*, 425 F.3d 1116, 1120. However, at this time, on State Farm's *motion to strike and dismiss*, it does not appear beyond doubt that Plaintiffs cannot establish an

class can be certified, but only whether Plaintiffs have stated a claim under Fed. R. Civ. P. 12(b)(6). Regardless of whether this Court ultimately decides to apply the law of New Jersey, the laws of the states of the class members, or some other scenario, Plaintiffs have met their burden under Fed. R. Civ. P. 12(b)(6). For purposes of this Motion, the Court can apply New Jersey law or the law where Plaintiffs reside, *i.e.,* New York, New Jersey, Illinois and California.

3. Plaintiffs have Article III standing

The issue of Article III individual standing to sue under a particular state statute (or common law) for individual recovery, and the ability to assert a claim under Fed. R. Civ. P. 23 on behalf of unnamed residents of other states, are logically separate. 1 Alba Conte & Herbert Newberg, NEWBERG ON CLASS ACTIONS § 2:9 (4th ed. 2002) ("Care must be taken, when dealing with apparently standing related concepts in a class action context, to analyze individual standing requirements separately and apart from Rule 23 class prerequisites. Though the concepts appear related, in that they both seek to measure whether the proper party is before the court, they are in fact independent criteria. They spring from different sources and serve different functions.").[9]

Here, Defendant does not directly attack Plaintiffs' standing under Article III to sue Bayer under the law of their home states. Rather, Defendant is attacking Plaintiffs' ability to bring claims in their own name in states in which they do not reside. However, Plaintiffs are not bringing claims in their own name in other states; rather they are seeking to represent similarly

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> actionable class action lawsuit. *See Parnes v. Gateway 2000, Inc.*, 122 F.3d 539, 546 (8th Cir. 1997). For example, Plaintiffs could possibly limit the multi-state class action to only include those states without conflicts of law, or possibly create a manageable number of sub-classes. Currently, it is unclear what state laws will be involved, or what claims will ultimately remain after the completion of class discovery.

Rios v. State Farm Fire & Cas. Co., 469 F. Supp. 2d 727, 741-42 (S.D. Iowa 2007) (emphasis in original).

[9] *See also Meyer v. CUNA Mut. Group*, 2006 U.S. Dist. LEXIS 4478, at *37 (W.D. Pa. Jan. 25, 2006) ("While there is no additional standing requirement for a plaintiff who seeks to represent a class, questions relating to Article III standing, however, frequently overlap and are sometimes confused with the criteria required for class certification embodied in Federal Rule of Civil Procedure 23(a).") (citations omitted); *In re NASDAQ Market-Makers Antitrust Litig.*, 169 F.R.D. 493, 504-05 (S.D.N.Y. Nov. 27, 1996) ("the question of standing is totally separate and distinct from the question of plaintiff's right to represent a purported class under Rule 23").

situated persons in other states. This latter issue is not one of Article III standing,[10] but rather will be addressed at class certification under Rule 23. Thus, "[t]he fact that the named Plaintiffs may not have individual standing to allege violations of consumer protection laws in states other than those in which they purchased Defendants' [product] is immaterial on a motion to dismiss a class action." *Ramirez v. Dollar Phone Corp.*, 2009 U.S. Dist. LEXIS 92972, at *24-25 (E.D.N.Y. Oct. 1, 2009) (internal quotations omitted).

A class representative's ability to assert claims on behalf of absent class members that reside in other states is evaluated under Fed. R. Civ. P. 23. At the class certification stage, under Rule 23, "[t]he relevant question [] is not whether the Named Plaintiffs have standing to sue Defendants – they most certainly do – but whether their injuries are sufficiently similar to those of the purported Class to justify the prosecution of a nationwide class action." *In re Grand Theft Auto Video Game Consumer Litig.*, 2006 U.S. Dist. LEXIS 78064, at *9-11 (S.D.N.Y. Oct. 25, 2006) (citing *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 377 (S.D.N.Y. 2002)); *In re Relafen Antitrust Litig.*, 221 F.R.D. at 269-70. Accordingly, this Court should reject Defendant's attempt to dismiss such claims prior to class certification as analytically premature. *See Ramirez*, 2009 U.S. Dist. LEXIS 92972, at *24-25.

[10] For standing under Article III, plaintiffs must be able to demonstrate: "(1) injury-in-fact, which is a 'concrete and particularized' harm to a 'legally protected interest'; (2) causation in the form of a 'fairly traceable' connection between the asserted injury-in-fact and the alleged actions of the defendant; and (3) redressability, or a non-speculative likelihood that the injury can be remedied by the requested relief." *W.R. Huff Asset Mgmt. Co. v. Deloitte & Touche LLP*, 549 F.3d 100, 106-07 (2d Cir. 2008) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992)), *cert. denied*, 129 S. Ct. 2011 (2009). Notably, in determining individual standing, courts are not concerned with the issue of whether the class representative can represent a class. Indeed, the three part test for standing focuses solely on the rights of the individual plaintiff. As a result, an individual that has a right to bring an individual claim under *any* state's law against one of the defendants has standing pursuant to Article III.

B. Plaintiffs Sufficiently Allege Their State-Law Claims

1. Plaintiffs adequately state Consumer Protection Act claims where Bayer deceptively marketed its Products

a) Plaintiffs allege that Bayer marketed the products in such a way as to misrepresent that the products were approved by the FDA

Bayer wholly mischaracterizes the nature of Plaintiffs' state-law claims. Bayer blindly asserts that Plaintiffs' state-law claims are based solely "on the allegation that Bayer failed to obtain FDA approval for" its Products. Def. Br. at 6-7. While one aspect of the factual story behind Plaintiffs' claims is Bayer's failure to obtain FDA approval, Plaintiffs' claims are actionable because of the second prong that Bayer ignores: Bayer not only failed to obtain FDA approval but *it marketed the products as if they had FDA approval*. *See, e.g.*, ¶¶ 5, 26, 27, 39, 41-43, 65. Marketing the products as if they had FDA approval is a violation of the state consumer protection acts at issue.[11]

Defendant makes much of the notion that the mere sale of a drug without any affirmative representations does not deceive consumers. However, the FDA has specifically found this assertion to be wrong. Specifically, as alleged in Plaintiffs' Complaint, in May 2000, the FDA's Associate Commissioner for Policy advised companies considering marketing products that combine or co-package dietary supplements and over-the-counter ("OTC") drug ingredients that:

> In addition, consumers may be confused about the degree of scrutiny FDA gives such combination products. Consumers may believe that both components have been subjected to the more stringent drug regulatory requirements when, in fact, only the drug component may have been reviewed by the agency for safety and effectiveness.

¶ 26 (citing http://www.ahpa.org/portals/0/pdfs/08_0529_AHPA_to_FDA_OTC_

[11] *See, e.g.*, 815 ILCS 510/2(a)(2), (a)(5) (2009) (deceptive practices defined to include, *inter alia*, causing "likelihood of confusion or of misunderstanding as to the ... approval, or certification of goods or services;" and representing "that goods or services have sponsorship, approval, characteristics, ... uses, benefits, ... that they do not have....").

DS_Combination_Products.pdf (last visited July 10, 2009)). The FTC and the Third Circuit have also found the premise of Bayer's argument to be wrong:

> Pervasive government regulation of drugs, and consumer expectations about such regulation, lend drug claims all the more power to mislead. The Commission's reasoning on this point (see especially App. 389 n. n**) is similar to that approved in *Simeon Management Corp. v. FTC*, *supra*, 579 F.2d at 1145 (footnote omitted):
>
> > The Commission found that (1) some consumers will reasonably believe that the government exercises control over the promotion and use of prescription drugs; (2) this belief is intensified by the advertisements' representations that the weight loss treatments are safe, effective and medically approved; and (3) the representations may therefore reasonably lead consumers into the mistaken belief that the claims of safety and effectiveness are based, not on the advertiser's own opinion, but on a determination by the FDA. It further found that, in view of the public's belief that the government strictly regulates drugs, the fact that the treatments involve administration of a drug lacking FDA approval for such use may materially affect a consumer's decision to undergo the treatment. *Accordingly, the Commission declared that the failure to disclose that the weight reduction treatments involve injection of a drug lacking FDA approval for such use renders the advertisements deceptive and thus in violation of § 5 of the FTCA.*
>
> The Commission in these proceedings reasonably extended the ideas approved in Simeon from prescription to non-prescription drugs, and from absolute representations about safety and effectiveness to comparative representations.

American Home Prods. Corp. v. FTC, 695 F.2d 681, 697-98 (3d Cir. 1982) (emphasis added).[12] Thus, Plaintiffs complain here because Defendant marketed the Products in such a way as to deceive consumers that FDA approval had been granted.[13] *Id.*

[12] The majority of consumer protection statutes, which generally prohibit unfair or deceptive trade practices, are based on the Federal Trade Commission Act ("FTCA"). *See* 15 U.S.C. § 41, *et seq.* The so-called "little FTC Acts" have been enacted in all fifty states and the District of Columbia. Jack E. Karns, *State Regulation of Deceptive*

Moreover, while Bayer now characterizes the Products as "combination aspirin and dietary supplement products," Def. Br. at 1, the heart of Plaintiffs' claim is that Bayer holds these products out as *drugs*, not as vitamins or dietary supplements. *See*, *e.g.*, ¶ 58 ("In a graphic depicting Bayer's aspirin products, *including Bayer Heart Advantage*, Bayer's website states "No other over-the-counter pain reliever has been around as long or has been researched as extensively as aspirin, nor has any been proven to be more effective.") (emphasis added). Plaintiffs allege that Bayer makes affirmative representations that are exactly of the type the FTC and Third Circuit have found deceptive. For example, Plaintiffs allege that, "on its website, Bayer provides misleading statements designed to confuse consumers that Bayer Heart Advantage – and specifically the phytosterols in combination with aspirin – has received regulatory approval. *See*, *e.g.*, ¶ 65 (Bayer states: "The FDA has recognized the use of phytosterols (at least 800mg a day in divided doses) as part of a low-fat diet to cut the risk of heart disease."). Here, not only does Bayer hold Heart Advantage out as a drug, it expressly represents that the FDA has looked at what the product is supposed to do. Bayer clearly intends to confuse consumers regarding the FDA's approval (or not) of its Combination Aspirin Product. Thus, Plaintiffs allege that the marketing of the Products as aspirin-based products in and of itself was deceptive given that it implied that the full product – and not just the aspirin component – had been reviewed by the FDA for safety and efficacy.[14]

Trade Practices Under "Little FTC Acts": Should Federal Standards Control?, 94 Dick. L. Rev. 373, 373 (1990). Moreover, twenty-six states "statutorily or judicially recognize a federal deference obligation" to Federal Trade Commission and federal court interpretations of the FTCA. *Id.* at 379.

[13] The FTC has also found that "[w]hen an analgesic advertiser [which Bayer is here] claims its product to be superior in performance, even without the additional explicit claim that it has been so proven, it is reasonable for consumers to construe that claim to be the assertion of a fact that is generally accepted, within the scientific community, as established. By their nature, therapeutic drug products raise special public health concerns, in light of the risks associated with their use." *American Home Prods. Corp.*, 695 F.2d at 696.

[14] While Bayer claims that the Products are, in part, a dietary supplement not requiring FDA-approval, Bayer fails to comply with the Dietary Supplement Health and Education Act ("DSHEA"). The DSHEA requires dietary supplements to show a specific "disclaimer" if a manufacturer makes certain claims on a dietary supplement label. *See* 21 U.S.C. § 343(r)(6). Specifically, the disclaimer provides: "This statement has not been reviewed by the

Contrary to Defendant's argument, courts do not allow corporations to market a drug (or any product) as having regulatory approval (or uses and benefits) that it does not. For example, in *Mutual Pharm.*, the plaintiff manufactured an FDA-approved drug called Qualaquin (used to treat the symptoms of malaria). *Mutual Pharm. Co. v. Ivax Pharms., Inc.*, 459 F. Supp. 2d 925, 940 (C.D. Cal. 2006). The defendants marketed *unapproved* competing drug products by placing them on private drug dispensing databases and pricing systems ("clinical/price lists"), such as First Databank and Medispan (the nation's two principal vendors of drug information databases), which represent a major drug-marketing communications channel to pharmacies. These clinical/price lists are routinely used by pharmacists to decide which drug brand to dispense to fill a prescription. *Id.* at 930-31, 939-40.[15]

The plaintiff filed a Lanham Act claim against the defendants. According to the plaintiff, marketing unapproved drugs through First Databank and Medispan falsely implied to pharmacists that the defendants' drugs were FDA-approved, when in fact, they were not. *Id.* at 940. Like Bayer, the defendants in *Mutual Pharm.* argued that false implications of FDA-approval were not actionable. *Id.* at 941. The district court disagreed.

First, the court explained that: "[s]o long as courts are not required to perform 'authoritative interpretation and direct application of FDA regulations,'" the fact that a matter

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Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." ¶ 26; Def. Br., at 14, n.8. Bayer contends in Footnote 8 that the disclaimer is inapplicable to Bayer's Products "where the dietary supplement is the subject of an unqualified health claim like calcium and phytosterols." *See* Def. Br. at 14 n.8. However, Bayer's marketing does not include only unqualified health claims.

Here, the label of Bayer Calcium proclaims that it "Provides 300mg of Calcium Which *Helps* Strengthen Bones To Help Fight Osteoporosis" while the Bayer Heart Advantage label claims to contain "Phytosterols, to *help* lower bad cholesterol..." ¶¶ 37, 64 (emphasis supplied). The company's use of the qualifiers "help" and "helps" on each combination aspirin's label requires that the disclaimer appear on the packaging (which it does not). As explained by the FTC, "[v]ague qualifying terms – for example, that the product 'may' have the claimed benefit or '*helps*' achieve the claimed benefit – are unlikely to be adequate" disclosures of qualifying information, and could mislead consumers. *See* Federal Trade Commission, *Dietary Supplements: An Advertising Guide For Industry* at 7 (April 2001) (emphasis added), http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.pdf. That is exactly what Plaintiffs have plead here, *i.e.* that they have been misled by Bayer's claims.

[15] A survey indicated that pharmacists generally believe all of the drugs contained on the clinical/price lists are FDA-approved. *Id.* at 939.

deals with an issue of FDA-approval does not bar a deceptive marketing claim (*e.g.*, a Lanham Act claim). *Id.* at 935.

Second, the district court explained:

> Mutual's argument concerning the particular marketing channel used by defendants as conveying the false impression of FDA approval is not insubstantial. Defendants argue that this misrepresentation consists of nothing more than a veiled argument that defendants are simply marketing a non-FDA approved drug. The Court reads the substance of Mutual's claim differently. It is not the simple act of defendants marketing a non-approved drug that Mutual seeks to combat, but the particular form that marketing has taken; a form that Mutual contends carries certain implicit false suggestions in the minds of the consumer that defendants' drug is FDA-approved.

Id. at 940. Third, the court found that the evidence sufficiently showed that marketing an unapproved drug through clinical/price lists could create a false impression of FDA-approval. *Id.* at 939-40.

The *Mutual Pharm.* court's reasoning is directly applicable here. Plaintiffs here do not complain simply that Defendant sold a product that was not FDA-approved. Instead, Plaintiffs complain, *inter alia*, that Defendant's marketing tactics for the unapproved drugs created a false impression of FDA-approval.

An analogous scenario was presented to the Tenth Circuit in the case of *Cottrell, Ltd. v. Biotrol Int'l, Inc.*, 191 F.3d 1248, 1253 (10th Cir. 1999). There, the plaintiff alleged false advertising of a cleaner/disinfectant to the effect that the EPA had approved the product when in fact such approval was not obtained. The defendant responded by urging that there is no private right of action under the Federal Insecticide, Fungicide, and Rodenticide Act or "FIFRA," 7 U.S.C. §§ 136-136y.[16] But the Tenth Circuit had no trouble distinguishing between a viable

[16] The court noted that the EPA's enforcement relationship to FIFRA is similar to the FDA's role under the FDCA. 191 F.3d at 1255.

Lanham Act claim "focus[ing] on [defendant's] representations directed at consumers" and an improper claim to enforce FIFRA. *Cottrell*, 191 F.3d at 1254 n.6; *see also id.* at 1255-56. The deceptive-marketing claim alleged that defendant's advertising deceived customers "by implying that EPA approval or clearance has been obtained [for the seven-day efficacy claim]." *Id.* at 1254. This claim encompassed the allegation that the defendant's advertising deceived consumers. This was sufficient to allege a material misrepresentation under the Lanham Act. *Id.* at 1255-56. Furthermore, *Cottrell* recognized that the claim at issue would not "inherently require interpretation of FIFRA regulations and/or EPA approvals." *Id.* at 1256. The claim would instead require the trial court to determine whether the defendant's representations falsely implied the EPA had approved the defendant's product effectiveness assertion, and, *Cottrell* concluded that "courts are capable of resolving such issues." *Id.*

In *Cottrell*, the court recognized that a private claim might not involve consumer deception, but rather, the mere violation of a federal labeling requirement. In such cases, the claim could be construed as "an attempt to enforce [the Act's] labeling requirements." *Id.* at 1255. But *Cottrell* ruled that these authorities "support a Lanham Act claim independent of FIFRA" by adding the allegation of consumer deception. *Id.* at 1255. According to the court, this claim "alleged sufficient facts to support a Lanham Act claim independent of FIFRA." *Id.*

Thus, this Court should not foreclose claims based, in part, on false implications of agency approval. As in *Cottrell*, Plaintiffs' claims involve more than just whether Bayer sells the Products without FDA approval.[17] Central to Plaintiffs' claims is whether Bayer's marketing

[17] Thus, Defendant's reliance on *Mylan Labs. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993), and the authorities on page 13 are misplaced. In *Mylan,* the court found that defendant had not made a misrepresentation actionable under the Lanham Act that its product was approved by the FDA merely by selling the product; however, other claims based upon other alleged misrepresentations were upheld. *Id.* at 1138

is likely to deceive consumers, which distinguishes Plaintiffs' claims from a disguised FDCA-enforcement action and Bayer's authorities.

The authorities on which Defendant relies are not applicable here. For example, Bayer relies on *Anthony v. Country Life Mfg.*, L.L.C., 2002 U.S. Dist. LEXIS 19445 (N.D. Ill. Oct. 7, 2002), *aff'd*, 2003 U.S. Dist. LEXIS 13622 (7th Cir. 2003). Unlike the Plaintiffs here, the *Anthony* plaintiff did not claim that the defendant marketed the products at issue as having FDA approval. Rather, the plaintiff argued that it was "immoral, unethical and unscrupulous" for the defendant to have knowingly placed 'adulterated' food bars into the stream of commerce under the Food, Drug and Cosmetic Act. *Id.* at *4. In fact, the court found important that the plaintiff did not allege she was deceived. *Id.* at *5 ("Anthony was not deceived...."). The allegations in *Anthony* thus stand in sharp contrast to the allegations of actual deception in this case. *See, e.g.*, ¶ 10 ("Mr. Blank was actually deceived in that he believed that Bayer's sale of Bayer Heart Advantage was the result of the FDA-approval process. He would not have purchased Bayer Heart Advantage had he known that Bayer had not submitted the product to the FDA."); ¶ 11 (same for Mr. Nosbisch); ¶ 12 (same for Mr. Vinson); ¶ 9 (same for Ms. Goldberg); ¶ 13 (same for Ms. Nosbisch except with respect to Bayer Calcium).

Further, Bayer relies on *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 2009 U.S. Dist. LEXIS 58697 (C.D. Cal. June 17, 2009).[18] However, *Epogen* was not about marketing a non-approved drug as being FDA-approved like Bayer did here. In fact, the

[18] All of the cases cited by Defendant in the pharmaceutical context specifically relate to prescription drugs. The market for – and the rules that apply to – prescription drugs are different than the over-the-counter ("OTC") market. In the prescription drug context, a doctor may prescribe a drug for a completely different use, or "off-label use," than those uses approved by the FDA. Thus, in that context, courts have struggled with whether "off-label" claims are actionable because the doctor made the prescribing decision, presumably based on scientific knowledge and experience.

Here, in the OTC market, there is no doctor or learned intermediary between the consumer and Bayer's marketing of the Products. Thus, there is no intermediary between the claims made by Bayer and the Plaintiffs and their purchasing decision. For this reason, "[t]he consumers of OTC analgesics are entitled, as a matter of marketplace fairness, to rely upon the manufacturer to have a sufficient kind and level of substantiation for the claim...." *American Home Prods.*, 695 F.2d at 694.

Epogen court specifically noted that it would not dismiss a case based on the allegations Plaintiffs make here. The court stated: "By way of example, if Amgen had falsely represented in its informational materials that EPO was FDA-approved for an off-label use, such conduct would almost certainly be fraudulent." *Id.* at *22.[19]/[20] Thus, *Epogen* supports denial of Bayer's motion to dismiss.

b) Plaintiffs allege that Bayer made misrepresentations and omissions separate from whether the products were FDA approved

Plaintiffs' claims should survive independently because they allege that Bayer mislead and deceived consumers into believing that the Products had been proven to be safe and effective for their marketed purposes. *See* Sections II.A.2 and II.A.3, *supra*. "Because consumers cannot accurately rate [OTC analgesics] for themselves, advertising, and the expectations which it engenders, becomes a significantly more influential source of consumer beliefs than it would otherwise be." *American Home Prods.*, 695 F.2d at 698 (citations omitted).

Like in *American Home Prods.*, there were plainly affirmative representations in the case at bar, and Defendant's marketing efforts went far beyond the mere sale of a drug. Most notably, Plaintiffs allege (and Defendant ignores) that Defendant misrepresented that the added ingredients in each Combination Aspirin help fight specific diseases long-term. Plaintiffs allege that these claims are deceptive because aspirin is not meant for long-term use, due to the fact that the long-term use of aspirin can cause serious side effects like gastrointestinal bleeding. ¶ 4.

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[19] Defendant also relies on *Braintree Lab., Inc. v. Nephro-Tech, Inc.*, 1997 U.S. Dist. LEXIS 2372, at *19 (D. Kan. Feb. 26, 1997); however, the court in *Braintree* stated: "Most obviously, a false statement of FDA approval is actionable."

[20] *See also McNeilab, Inc. v. American Home Prods. Corp.*, 501 F. Supp. 517, 543 (S.D.N.Y. 1980) (stating that "the representation that [defendant's product] is the maximum strength 'allowed' is a statement which suggests positively that a legally competent authority has affirmatively approved the use of [defendant's] product – which is, of course, not the case" and finding that defendant's advertisement was "actually false" where "the FDA has not affirmatively authorized the sale of [defendant's] products ... and [defendant] did not contend that any other entity with authority to regulate such products had done so").

Yet Bayer markets Bayer Calcium both as a "CALCIUM SUPPLEMENT" and for "ASPIRIN REGIMEN" use. ¶ 36. Bayer markets the product with a picture of a daily glass of milk, and discusses daily "adequate calcium intake." ¶¶ 37-38. Bayer thus markets Bayer Calcium as a daily dietary source of calcium like milk. *Id.* *See also id.* ¶ 41(d) ("It has been proven that regular aspirin use can prevent 1 out of 4 heart attacks among patients with a previous event").

Similarly, Bayer markets Heart Advantage as a way for consumers to lower their risk of heart disease by commencing an aspirin regimen. ¶ 66. Bayer also encourages consumers, on the carton labeling, to use Bayer Heart Advantage twice a day to lower their cholesterol. ¶¶ 64, 67. However, a daily aspirin regimen should only consist of a single 81mg tablet. ¶¶ 37, 64, 67.

Where an OTC analgesic manufacturer exhorted consumers to do exactly what Bayer is here – take more aspirin or use it long term – the FTC and the Third Circuit found that the advertising claims required particular attention given safety concerns. The Third Circuit stated: "The larger dosages of aspirin which AHP exhorts consumers to ingest increase the dangers of adverse side effects, with little evidence that there exist any countervailing benefits." *American Home Prods.*, 695 F.2d at 698. *See also id.*, at 699 and n.31 (listing side effects from aspirin, "which range from massive gastrointestinal bleeding (which may be fatal) to hepatic (liver) dysfunctions.") (citations omitted).

The same concern is mirrored here in Bayer's advertising claims. Plaintiffs allege that:

> "[]Bayer's Products ... claim that the added ingredients in each medicine help fight specific diseases long-term. ¶ 3. However, taking aspirin long-term should be under a doctor's supervision, as the medicine is meant for short-term use. The long-term use of aspirin can cause serious side effects like gastrointestinal bleeding." ¶¶ 3-4. *See also* ¶¶ 35-38 (describing marketing claims for Women's Calcium for long-term use to mitigate, treat and/or prevent cardiovascular problems and osteoporosis); ¶¶ 40-41, 61-

> 64, 66 (describing marketing claims for Bayer Heart Advantage for long-term daily use in preventing or treating cardiovascular diseases). Accordingly, Plaintiffs' consumer protection act claims should survive.

Plaintiffs also allege that Bayer Hearth Advantage cannot do what Bayer represented it to do. For example, with respect to Bayer Heart Advantage, Plaintiffs allege, *inter alia*:

> 67. To provide any putative benefit, the dosage of phytosterols necessary to be consumed equals 2 tablets of Bayer Heart Advantage. By contrast, a daily aspirin regimen consists of a single 81mg tablet. ***Thus, a person cannot simultaneously ingest the recommended dose of aspirin while obtaining any purported cholesterol lowering effects of phytosterols.***

¶ 67. However, no where does Bayer disclose this fact. "Failure to disclose that a claim regarding a drug lacks an *appropriate* level of support, when such support is non-existent, is misleading."[21] *American Home Prods.*, 695 F.2d at 697 (emphasis in original).

In fact, the manufacturer of Bayer Aspirin, then known as Sterling Drug, has already been warned about making advertising claims for which it does not have substantiated support. In *Sterling Drug, Inc. v. FTC*, 741 F.2d 1146 (9th Cir. 1984), the FTC found that, while the manufacturer of Bayer had represented in advertising that Bayer Aspirin's therapeutic effectiveness had been established by scientific means, the claim was not supported by scientifically acceptable evidence. *Id.* at 1148. The Commission entered an order against the manufacturer, which required, in part, the manufacturer "to have a reasonable basis to support

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[21] The Administrative Law Judge in the original proceeding against AHP defined the level of support needed to substantiate these types of claims as follows:

> The consumers of OTC analgesic products are entitled, as a matter of marketplace fairness, to rely upon the manufacturer to have a sufficient kind and level of substantiation for the claim. In the circumstances of this case, the only sufficient substantiation for the claim is that the claim is accepted as established by the medical-scientific community. The record is clear that, with respect to OTC [over the counter, i.e., non-prescription] internal analgesic products, the medical-scientific community requires two or more well-controlled clinical studies . . .

American Home Prods. Corp., 695 F.2d at 694 (citations omitted).

therapeutic performance claims for any of its nonprescription internal analgesic products." *Id.* at 1156. On appeal to the Ninth Circuit, the manufacturer claimed that the reasonable basis requirement was too vague. *Id.* Affirming this portion of the order, the Ninth Circuit "conclude[d] that this portion of the order is sufficiently clear and precise," and stated:

> If Sterling prefers to continue to advance claims of therapeutic efficacy, it can reduce its risk of violating the order in one of several ways. First, it can support its therapeutic efficacy claims with two well-controlled clinical studies. Second, it can secure from the Commission an advisory opinion as to the propriety of proposed advertising. *See id.* at 394. Third, it can advise consumers that its claims of therapeutic efficacy are not clearly established. *See American Home*, 695 F.2d at 695.

Id. at 1157. The FTC's and Ninth Circuit's analysis is directly applicable here.

Plaintiffs allege that Bayer Heart Advantage cannot have the therapeutic effects Bayer represents the product can have at the doses required. ¶¶ 65-67. Yet no where does Bayer "advise consumers that its claims of therapeutic efficacy are not clearly established." *Sterling*, 741 F.2d at 1157. Accordingly, Plaintiffs have adequately alleged that Bayer made misrepresentations and omissions that deceived them and the Motion To Dismiss should be denied.

c) Plaintiffs have adequately alleged an injury

Bayer argues that Plaintiffs have failed to allege an injury because, according to Bayer, the Products were effective. Bayer's argument, however, relies on its unproven assumption concerning the efficacy of the Products. Moreover, Bayer ignores the well-settled law that consumers suffer an injury when they are deceived by misleading marketing into purchasing a product that was something other than what they bargained for. Here, Plaintiffs have alleged that they were deceived into purchasing a product that they believed was submitted to the FDA for

approval and was proven to be safe and effective. ¶¶ 5, 9, 10, 11, 12, 13. Under New Jersey law, and the laws of the other states, Plaintiffs have sufficiently alleged a cognizable injury.

(1) Plaintiffs have suffered an "ascertainable loss"

To satisfy the injury element of the New Jersey Consumer Fraud Act, a consumer need only allege that they have suffered an "ascertainable loss." *Ramirez v. STI Prepaid LLC*, 2009 WL 737008, at *3 (D.N.J. Mar. 18, 2009). "'[A]scertainable loss, ... has been broadly defined as embracing more than a monetary loss. An ascertainable loss occurs when a consumer receives less than what was promised.'" *Id.* (quoting *Union Ink. Co., Inc. v. AT&T Corp.*, 352 N.J. Super. 617, 646, 801 A.2d 361, 379 (App. Div. 2002)); *see also Strzakowlski v. General Motors Corp.*, 2005 WL 2001912, at *7 (D.N.J. Aug. 16, 2005) (same).

For example, in *Miller v. American Family Publishers*, 284 N.J. Super. 67, 91, 663, A.2d 643, 655 (Law Div. 1995), the court held that plaintiffs suffered an ascertainable loss when "[f]or their money, they received something less than, and different from what they reasonably expected in view of defendant's presentations." Here, Plaintiffs expected that the Products were FDA approved, but instead received a product that they would not have purchased but for Bayer's deceptive marketing.

Indeed, the United States Court of Appeals for the Second Circuit has held that plaintiffs have suffered a cognizable injury when they purchased a product as a direct result of defendant's deceptive acts instead of less expensive alternatives. *Desiano v. Warner-Lambert Co.*, 326 F.3d 339, 349 (2d Cir. 2003) (applying New Jersey law). In *Desiano*, plaintiff health insurers brought a lawsuit under the New Jersey Consumer Fraud Act alleging that defendants misrepresented the safety of a prescription drug for the treatment of diabetes, Rezulin, and seeking to recover monies spent purchasing the drug. The district court granted defendants' motion to dismiss, concluding that Rezulin did not harm, but benefitted many, and thus plaintiffs could not recover

damages for patients who were not harmed. *Id.* at 347. The Second Circuit vacated and remanded the district court's decision. In finding error by the district court, the Second Circuit concluded that the injury analysis was "unaffected by whether any given patient who ingested Rezulin became ill" because "Plaintiffs' claim is that the Defendants' wrongful action was their misrepresentation of Rezulin's safety, and that this fraud directly caused economic loss to them as purchasers, since they would not have bought Defendants' product, rather than available cheaper alternatives, had they not been misled by Defendants' misrepresentations." *Id.* at 349.

Like Bayer, defendants in *Desiano* contended that, if their product "had been effective in all ... patients without any side effects, plaintiffs would have no basis for a claim." *Id.* However, the Second Circuit rejected that argument, stating "it is easy to see how Defendants' reasoning is flawed." *Id.* To illustrate the flaws in the defendants' logic – "logic" which Bayer mimics here – the Second Circuit explained:

> Consider, for example, a hypothetical in which a defendant drug company markets a 'new' much more expensive drug claiming it is a great advancement (safer, more effective, etc. than metformin – the standard diabetes drug) when in fact the company is simply replicating the metformin formula and putting a new label on it. In other words, the only difference between metformin and the 'new' drug is the new name and the higher prescription price (paid almost entirely by the insurance company). In that case, the 'new' drug would be *exactly* as safe and effective as metformin, and thus there could be no injury to any of the insurance company's insured. Nevertheless, the insurance companies would be able to claim precisely as they do here – that the defendants engaged in a scheme to defraud it, and that the company suffered direct economic loss as a result.

Id. at 349-50 (emphasis in original).

The case at bar is wholly analogous to the Second Circuit's hypothetical, especially as consumers paid the price of the drug and thus suffered the direct economic injury. Plaintiffs here allege that they were deceived into buying aspirin products without the required regulatory

approval and that were not safe and effective for their marketed purposes. ¶¶ 1, 6. The Complaint further alleges that "[b]ased on Bayer's misleading and deceptive sales scheme, Bayer was able to and did charge a premium for the illegal Products over the costs of approved OTC aspirins." ¶ 81. None of the Plaintiffs would have purchased the Products had they known that Bayer had not submitted the product to the FDA. ¶¶ 9-13, 84. Accordingly, the Complaint alleges that each plaintiff (and class member) who purchased a Product suffered the direct economic injury that the Second Circuit held to be actionable in *Desiano*.

The *Desiano* court's reasoning has been adopted by courts throughout the country. For example, in *In re Bextra & Celebrex Mktg., Sales Practices & Prod. Liab. Litig.*, 2007 WL 2028408 (N.D. Cal. July 10, 2007), the court denied defendants' motions to dismiss holding that plaintiffs adequately alleged an injury by claiming that "plaintiffs purchased Celebrex instead of traditional NSAIDs because defendants misrepresented that Celebrex is better than traditional NSAIDs; in other words, plaintiffs could have and would have received exactly the same relief at a much lower cost but for defendants' deception." *Id.* at *5; *accord In re Zyprexa Prod. Liab. Litig.*, 493 F. Supp. 2d 571, 576-77 (E.D.N.Y. 2007); *In re Actiq Sales & Mktg. Practices Litig.*, 2009 WL 1444443, at *3, 4 (E.D. Pa. May 22, 2009); *In re Lupron Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d 148, 175, 181 (D. Mass. 2003).

Similarly, in *Smith v. Wm. Wrigley Jr. Co.*, 2009 WL 3172771 (S.D. Fla. Oct. 1, 2009), the court denied defendant's motion to dismiss where plaintiffs claimed that they were injured because they paid a premium price for defendant's product as a result of defendant's misleading marketing campaign. Specifically, in *Smith*, the defendant touted that its Eclipse® chewing gum contained "Magnolia Bark Extract, a natural ingredient scientifically proven to kill the germs that cause bad breath." *Id.* at *1. However, defendant's so-called "scientific proof" was inadequate

or irrelevant. *Id.* The *Smith* plaintiffs alleged that as a result of the misleading claims, defendant was able to charge a premium price. *Id.* at *3. Recognizing that plaintiffs "'claim[] an actual injury in the form of insufficient product value [as] she contends that she did not get what she bargained for,'" the *Smith* court concluded that plaintiffs adequately stated a claim for misleading and unfair trade practices. *Id.* (quoting *Collins v. Daimler-Chrysler Corp.*, 894 So. 2d 988, 990-91 (Fla. Dist. Ct. App., 5th Dist. 2004)).

Like the plaintiffs in *Desiano* and *Smith*, Plaintiffs would not have purchased the Products had they known the truth: the Products were not approved by the FDA, were not safe and effective for their marketed purposes, and should never have been sold. Because consumers paid for a product that never should have been available in the marketplace, they have suffered a direct economic injury. *See Maniscalco v. Brother Int'l Corp. (USA)*, 627 F. Supp. 2d 494, 503 (D.N.J. 2009) ("it is sufficient if a plaintiff avers that 'had the alleged defect been disclosed, consumers would not have purchased [defendant's product].'") (quoting *McCalley v. Samsung Elec. Am., Inc.*, 2008 WL 878402, at *9 (D.N.J. 2008)) (alteration in original).[22]

(2) Bayer mischaracterizes Plaintiffs' damages theory

Despite Bayer's repeated mantra, Plaintiffs have not pled a "price inflation" or "price impact" theory of damages. To the contrary, pursuant to *Desiano* and its progeny, Plaintiffs contend that they never would have purchased Products had they known of Bayer's deception. Thus, this is not a case in which market forces drove up the price of the product. Rather, Plaintiffs seek a refund of the purchase price for the Products. ¶ 84. Alternatively, Plaintiffs will

[22] Bayer asserts that Plaintiffs lack standing because they have not suffered an "injury-in-fact." However, as demonstrated above, Plaintiffs have indeed suffered an injury as they purchased a product they otherwise would not have as a result of Bayer's false and misleading marketing. Thus, Plaintiffs have exceeded the "low threshold" to establish standing. *See Ross v. Bank of Am., N.A.*, 524 F.3d 217, 222 (2d. Cir. 2008) ("Injury in fact is a low threshold...."). In *Ross*, the district court dismissed the complaint after finding that the plaintiffs had not sufficiently alleged an injury in fact. The Second Circuit reversed.

seek recovery under the benefit of the bargain[23] or out of pocket loss[24] methods of calculating damages.[25]

Bayer's reliance on "price inflation/price impact" cases is therefore misplaced. For example, in *McLaughlin v. American Tobacco Co.*, 522 F.3d 215, 229-30 (2d Cir. 2008), the Second Circuit concluded that a "price impact" theory could not be pursued an a class-wide basis because plaintiffs had not adduced sufficient facts after discovery to demonstrate that the price impact model resulted in demonstrable damages. However, the *McLaughlin* analysis is inapplicable to the pending motion. First, *McLaughlin* was a class certification opinion decided on a fully developed factual record. Second, plaintiffs in *McLaughlin* asserted RICO claims, which have specific injury requirements that are not at issue here. Finally, and most significantly, Plaintiffs here do not claim that market forces impacted the price of the Products.

Bayer's reliance on *International Union of Operating Engineers Local No. 68 Welfare Fund v. Merck & Co., Inc.*, 192 N.J. 372, 929 A.2d 1076 (N.J. 2007) ("*Merck*"), is similarly misplaced. In *Merck*, the New Jersey Supreme Court addressed a motion for class certification in which plaintiffs asserted "the price charged for Vioxx was higher than it should have been as a

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[23] *See, e.g., Smith, Allen, Mendenhall, Emons & Selby v. Thomson Corp.*, 371 Ill. App. 3d 556, 559 (Ill. Ct. App. 2006) ("Illinois courts have adopted the benefit-of-the-bargain rule, whereby damages are determined by assessing the difference between the actual value of the product sold and the value the product would have had at the time of the sale if the representations had been true."); *Furst v. Einstein Moomjy, Inc.*, 860 A.2d 435, 442 (N.J. 2004) ("The merchant who promises to deliver a product at a particular price must, at the option of the consumer, either deliver the product or render its replacement value."); *Cortez v. Purolator Air Filtration Prods. Co.*, 23 Cal. 4th 163, 174 (2000) (restitution is "the return of the excess of what the plaintiff gave the defendant over the value of what the plaintiff received"). *See also Stephenson v. Capano Dev., Inc.*, 462 A.2d 1069, 1076 (Del. 1983) ("The aim of this [the benefit of the bargain] method [of calculating damages] is to put the plaintiff in the same financial position that he would have been in if the defendant's representations had been true."); *Lowrey v. Dingmann*, 86 N.W.2d 499, 502 (Minn. 1957) ("the measure of damages is the difference between the actual value of the property received and the price paid for it"); *Zanakis-Pico v. Cutter Dodge, Inc.*, 47 P.3d 1222, 1233 (Haw. 2002) ("In fraud or deceit cases, the measure of pecuniary damages is usually confined to either the 'out-of-pocket' loss ... or the 'benefit of the bargain'...."); *Yost v. Millhouse*, 373 N.W.2d 826, 830 (Minn. Ct. App. 1985) (Damages under the Minnesota consumer fraud statute are calculated, as are damages under Minnesota law for fraudulent representations inducing a contract, using the "out-of-pocket" rule: "[t]he measure of [actual damages] is the difference between what the defrauded person paid and what he or she received.").

[24] *See, e.g., Cayuga Harvester, Inc. v. Allis-Chalmers Corp.*, 465 N.Y.S.2d 606, 618 (N.Y. App. Div. 4th Dep't 1983) (noting that New York follows the "out of pocket" method, and stating: "Stated simply, fraud damages are to give the plaintiff what he lost because he made the bargain....").

[25] Plaintiffs will make their disclosures at the appropriate time pursuant to Fed. R. Civ. P. 26(a)(2).

result of defendant's fraudulent marketing campaign." *Id.* at 392, 929 A.2d at 1088. Not only is *Merck* procedurally inapplicable, the damages theory rejected in that case has not been pled here.[26]

The difference between the damages theory that Bayer attempts to attribute to Plaintiffs and the refund theory Plaintiffs *actually* have pled is explained at length in *Ford Motor Co. E-350 Van Prods. Liab. Litig.*, 2008 WL 4126264 (D.N.J. 2008) ("*Ford Motor Co.*"), in which the court, on a motion to dismiss, upheld plaintiffs' damages theory. In *Ford Motor Co.*, plaintiffs alleged that certain Ford 15 passenger vans were defectively designed due to a high center of gravity that leads to high rollover rates. Although no class members suffered a rollover, plaintiffs claimed economic harm because the defect made the product unsuitable for transporting 15 passengers. Like Bayer, Ford argued that plaintiffs could not recover economic damages. In rejecting Ford's argument, the court distinguished allegations of "price inflation" from the refund theory asserted in this case as follows:

> Here, however, Plaintiffs do not expressly nor impliedly, plead such a [price inflation] theory. Rather, the Court finds that Plaintiffs adequately allege causal nexus distinguishable from fraud on the market. Plaintiffs allege that 'Ford's conduct herein is an unfair practice that has the capacity to, and did, deceive customers into believing that they were purchasing a vehicle that could be used safely, legally and practically to accommodate and transport 15 passengers.' Construing Plaintiffs' allegations in the light most favorable to them, the Complaint charges that Ford's alleged violations led to Plaintiff's damages by virtue of Ford's misrepresentations and omissions directed at Plaintiffs as direct customers. These facts differ from fraud on the market, because under that theory, a plaintiff must allege 'only that the price charged' for the product at issue 'was higher than it should have been as a result of defendant's fraudulent marketing campaign.'

[26] Likewise, *New Jersey Citizen Action v. Schering-Plough Corp.*, 367 N.J. Super. 8, 842 A.2d 174 (App. Div. 2003) ("*Schering-Plough*"), *Heindel v. Pfizer Inc.*, 381 F. Supp. 2d 364 (D.N.J. 2004), and *Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171 (D.D.C. 2003) are inapposite because Plaintiffs' damages theory is not dependent upon market demand. Moreover, in *Merck*, *Schering-Plough*, *Heindel*, and *Williams* prescription drugs were at issue. Thus, a consumer was not necessarily buying a product based solely upon a misleading advertising campaign, but also at the recommendation of a physician.

> *Merck*, 192 N.J. at 392. In other words, a party pursues fraud on the market, or 'price inflation theory' when it alleges that 'the fact of advertising the products caused the prices to rise for both the ones that are effective and for these, allegedly ineffective products as well.' *Schering-Plough*, 367 N.J. Super. at 15, 16. Yet here, Plaintiffs allege that Ford's fraudulent acts and omissions caused Plaintiffs' damages in the form of diminution in value and loss of use. They do not claim that the price charged for the allegedly unsafe vehicles was inflated by a broad advertising campaign. Thus, unlike the plaintiffs in *Merck* and *Schering-Plough*, Plaintiffs here do not pursue the price inflation theory, nor otherwise allege circumstances associated with a 'change in price' on the market. *Merck*, 192 N.J. at 392.

2008 WL 4126264, at *28. The *Ford Motor Co.* court thus concluded that plaintiffs sufficiently alleged a theory of damages, especially "[g]iven the 'hesitation' urged by New Jersey courts in approaching motions to dismiss New Jersey CFA claims." *Id.*[27]

Like plaintiffs in *Ford Motor Co.*, Plaintiffs here have not alleged that Bayer's false advertisements caused the price of the Products to rise. Rather, Plaintiffs argue that they would not have purchased a product that had not been FDA-approved and was not safe and effective for its marketed purposes. Thus, the Court should reject Bayer's efforts to miscast Plaintiffs' damages theory.[28]

2. Plaintiffs adequately plead their breach of warranty claims

Again, Defendant mischaracterizes Plaintiffs' claims. Plaintiffs' breach of warranty claims are not solely based on whether the Products satisfy FDA requirements. Rather, this case is about Bayer's deceptive marketing, advertising and promotion of its Products. The FDA's

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[27] The *Ford Motor Co.* court also refused to dismiss plaintiffs' warranty claims. In so doing, the *Ford Motor Co.* court distinguished another case on which Bayer relies, *Yost v. General Motors Corp.*, 651 F. Supp. 656, 657 (D.N.J. 1986). In *Yost*, the plaintiff alleged only that damage is "likely" or "may" occur. However, the *Ford Motor Co.* court concluded that the plaintiffs sufficiently alleged injury because they lost use of the van's full capacity. *Ford Motor Co.*, 2008 WL 4126264, at *15.

[28] *Parker v. Howmedica Osteonics Corp.*, 2008 U.S. Dist. LEXIS 2570 (D.N.J. Jan. 14, 2008), a case which contains an express notice that it is "NOT FOR PUBLICATION" provides no support to Bayer. In *Parker*, the court dismissed a complaint without prejudice for failure to plead sufficient facts to establish their loss. Thus, the *Parker* case is factually distinguishable.

warnings to Bayer merely provide the factual context for the breach of warranties and directly illustrate Bayer's inability to substantiate its marketing claims.[29] Accordingly, Plaintiffs' claims are about the making of promises that Bayer simply had no basis to make.

In general terms, a breach of express warranty arises from a promise made by a seller. The promise creates a warranty that the goods shall conform to and have the attributes set forth in the promise. *See Cippolone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (citing N.J. STAT. ANN. § 12A:2:13). The manufacturer's liability for breach of the warranty derives from, and is measured by, the terms of the warranty. *Id.* at 525. In other words, it is the manufacturer that defines the scope of its liability by warranting that its products will have certain characteristics.

Here, Bayer claims that the unique combination of aspirin and calcium in Bayer Calcium helps to "fight" osteoporosis. ¶ 37. Bayer has no basis to make the claim that calcium, alone or in combination with aspirin, is effective at combating osteoporosis.[30] ¶¶ 37, 39. There is no scientific support for Defendant's claim that this product will "fight" or otherwise treat osteoporosis.[31] In claiming that Bayer Calcium fights osteoporosis, Bayer is warranting that its Product has a characteristic that it simply does not have. Thus, Plaintiffs' warranty claims are based upon Bayer's unsupported "promise" to Plaintiffs and the Class that Bayer Calcium "fights" osteoporosis.

Similarly, Bayer claims that Bayer Heart Advantage includes "cholesterol lowering phytosterols" and states "[p]hytosterols help lower bad cholesterol." Bayer thus warrants to

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[29] Similarly, Plaintiffs' allegations that they purchased the Products believing that the claims were FDA-approved are nothing more than shorthand for the thrust of Plaintiffs' warranty claims – that Plaintiffs believed Bayer's claims were true.

[30] *See* 21 C.F.R. § 101.72. The only claim which is scientifically supported for calcium is that it may have an impact on reducing the risk of *developing* osteoporosis. *Id.* There is no basis whatsoever for Bayer to claim that calcium, alone or in combination with aspirin, is effective in "*fighting*" osteoporosis.

[31] The FDA warning letter merely points out the fact that Bayer is making a claim that it has no basis to make. The warning letter does not, however, create the basis for the warranty claim.

Plaintiffs and the Class that this Product is capable of treating, mitigating or preventing hypercholesterolemia and coronary heart disease. There is, however, no scientific basis to make such a claim.[32] Quite simply, there is no generally recognized scientific evidence that phytosterols, alone or in combination with aspirin, are capable of treating life threatening diseases like heart disease or hypercholesterolemia.

In support of its position that Plaintiffs have failed to allege warranty claims Defendant cites a series of cases from various jurisdictions. Even the most cursory reading of those cases reveals that they are wholly inapplicable to the case at hand.[33]

The primary case Bayer cites in support of its motion for dismissal of Plaintiffs' warranty claims, *In re Schering-Plough Corp. Intron*, 2009 U.S. Dist. LEXIS 58900 (D.N.J. July 10, 2009), *did not even involve warranty claims*. In *Schering*, the court dismissed plaintiffs' civil RICO and New Jersey consumer fraud claims based primarily on the absence of allegations that the pharmaceutical products were ineffective for their off-label applications. *See, e.g, id.,* at *36 ("Under [plaintiffs'] theory of injury, it matters not that individual consumers receive an effective drug that works as good as or better than expected. "). Here, on the other hand, Plaintiffs allege precisely what the court found lacking in *Schering*, *i.e.*, that Bayer's Products are not capable of doing what Bayer warrants they are capable of doing. *See Jackson v.*

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[32] *See* 21 C.F.R. § 101.83.

[33] The following cases cited by Bayer bear no resemblance to the allegations set forth in the Master Complaint. *See American Suzuki Motor Corp. v. Superior Ct.*, 37 Cal. App 4th. 1291, 1299 (Cal. 1995) (in a case concerning the claimed propensity of a small SUV manufactured by the defendant to roll over under certain circumstances, the court held that since the majority of vehicles sold to the putative class members had not rolled over, they remained fit for their ordinary purpose); *State Farm Cas. Co. v. Miller Elec. Co.*, 562 N.E.2d 589 (2d Cir 1990) (in a case concerning a house fire that was attributed to an allegedly defective extension cord, the jury found that the subject extension cord was not defective when it left the defendant manufacturer's possession); *Adams v. Peter Tramontin Motor Sales, Inc.*, 42 N.J. Super. 313, 325 (App. Div. 1956) (in a case concerning the sale of a 1955 Pontiac automobile, the court held that no warranty arose from a salesman's puffery that a particular 1955 Pontiac was "perfect" for the plaintiff and held that a breach of implied warranty did not lie where the vehicle merely required the usual "shakedown" period and some minor adjustments to put it in good working order); *Ryion v. Len-Co Lumber Corp.*, 543 N.Y.S.2d 595 (4th Dep't 1989) (ruling that it was not reversible error for a trial court to refuse to submit a claim for breach of implied warranty to a jury where the jury had been presented with claims for strict products liability).

Balanced Health Prods., 2009 U.S. Dist. LEXIS 48848 (N.D. Cal. June 10, 2009) (denying motion to dismiss breach of warranty claims where plaintiffs allege that the inclusion of a prescription drug, Bumetanide, in StarCaps breaches Defendants' promise that the product was "all natural.") Accordingly, the motion to dismiss should be denied.

3. Plaintiffs adequately plead their unjust enrichment claims

A claim for unjust enrichment "is based on 'an obligation which the law creates, in the absence of any agreement, when and because the acts of the parties or others have placed in the possession of one person money, or its equivalent, under such circumstances that in equity and good conscience he ought not to retain it, and which ex ae quo et bono belongs to another.'" *In re Chateaugay Corp.*, 10 F.3d 944, 957-58 (2d Cir. 1993) (quoting *Miller v. Schloss*, 218 N.Y. 400, 407, 113 N.E. 337 (1916)). In order to prove such a claim under New York law, a plaintiff must demonstrate: "(1) that the defendant benefitted; (2) at the plaintiff's expense; and (3) that equity and good conscience require restitution." *Beth Israel Med. Ctr. v. Horizon Blue Cross & Blue Shield of N.J., Inc.*, 448 F.3d 573, 586 (2d Cir. 2006) (citations and internal quotation marks omitted).[34] Plaintiff have adequately alleged these elements.

Plaintiffs allege that Bayer benefitted from its unlawful acts by receiving payments for the sales of the Products. ¶ 141. Without knowledge that the Products did not have regulatory approval nor that Bayer misrepresented their safety and efficacy, Plaintiffs conferred upon Defendant payment for such Products, benefits that were non-gratuitous. ¶ 142. Defendant accepted or retained the benefits conferred by Plaintiffs, with full knowledge and awareness that

[34] *See also Labajo v. Best Buy Stores, L.P.*, 478 F. Supp. 2d 523, 528 (S.D.N.Y. 2007) (noting that "There is, however, no real conflict between the laws of California and New York for … unjust enrichment. *Compare … Kidz Cloz, Inc. v. Officially for Kids, Inc.*, 320 F. Supp. 2d 164, 177 (S.D.N.Y. 2004), *with Lectrodryer v. SeoulBank*, 77 Cal. App. 4th 723, 91 Cal. Rptr. 2d 881, 883 (Cal. Ct. App. 2000) (elements for unjust enrichment)."); *People ex rel. Hartigan v. E & E Hauling, Inc.*, 607 N.E.2d 165, 177 (Ill. 1992) (Under Illinois law, "[t]o recover under this theory, plaintiffs must show that defendant voluntarily accepted a benefit which would be inequitable for him to retain without payment."); *VRG Corp. v. GKN Realty Corp.*, 135 N.J. 539, 554, 641 A.2d 519, 526 (1994) (Under New Jersey law, "[t]o establish unjust enrichment as a basis for quasi-contractual liability, "a plaintiff must show both that defendant received a benefit and that retention of the benefit would be unjust.").

Plaintiffs were not receiving Products of high quality, nature, fitness or value as Bayer represented. ¶ 143. Plaintiffs allege that Bayer's retention of the non-gratuitous benefits is unjust and inequitable. ¶ 144. "If the allegations contained in the complaint are true, then there is no question that the Defendant[] reaped financial benefits at the Plaintiffs' expense and that equity would require the Defendant[] to make restitution under such circumstances." *Allstate Ins. Co. v. Rozenberg*, 590 F. Supp. 2d at 395.

4. Plaintiffs could plead additional details in support of their state-law claims should the Court so require

Under Rule 15(a), leave to amend "shall be freely granted when justice so requires." Motions for leave to amend should be denied only for reasons such as undue delay, bad faith, futility of the amendment or prejudice to the other party. *See Foman v. Davis*, 371 U.S. 178, 182 (1962); *Aetna Cas. & Sur. Co. v. Aniero Concrete Co.*, 404 F.3d 566 (2d Cir. 2005). Here, amendment would not be futile. Plaintiffs could certainly allege a myriad of additional facts, including, but not limited to, regarding information within each Plaintiff's knowledge as to why they were deceived (*see* Def. Br. at 13-14), additional information concerning the manner in which Bayer marketed the Products,[35] and could restate their warranty claims to focus on the disease promises.[36] Accordingly, in the event that this Court is inclined to dismiss all or a part of Plaintiffs' claims, Plaintiffs respectfully request leave to file an amended complaint.

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[35] Such information could include, but would not be limited to, the manner in which Bayer placed the Products on retail pharmacy shelves among FDA-approved OTC products rather than in the nutritional supplement aisles. *See, e.g.,* www.commissaries.com/business/planogram/pdf_planograms/Analgesics_id13.pdf (planogram for the Defense Commissary Agency (which operates commissaries for U.S. military) reflecting that the Products are marketed by Bayer among OTC drugs and not on nutritional supplement or vitamin shelves) (last accessed October 21, 2009). Plaintiffs could also allege that Bayer hires and uses Planogram/Category Analysts to perform the function of analyzing and placing its products in these particular spots on retail pharmacy shelves in order to push the product's particular message (in this case, *inter alia,* FDA-approval). *See, e.g.,* http://www.careerbuilder.com/JobSeeker/Jobs/JobDetails.aspx?job_did=J3G46K6PTYG1PMH9M7G&cbRecursionCnt=1&cbsid=6eb586e3b6c4465cb4fac0b33d4e261e-309460288-VS-4&ns_siteid=ns_us_g_bayer_aspirin_planogr (Bayer job ad seeking a "Planogram/Category Analyst" to "work closely with Walgreens providing perspective and recommendations for … Shelving…." (last accessed October 21, 2009).

[36] *See* Section III.B.2, *infra.*

C. Plaintiffs' Claims Are Not Preempted

Bayer's preemption arguments should be unequivocally rejected. Bayer argues that Plaintiffs' action is preempted because it is based *solely* on Bayer's FDCA violations. Def. Br. at 17-19, 21. However, Plaintiffs allege state law violations independent of Bayer's FDCA violations, such as Bayer's marketing of the purported benefits from the Products and how such benefits cannot be obtained through a daily aspirin regimen. Bayer's preemption arguments thus necessarily fail.

1. Plaintiffs' claims are not preempted where plaintiffs allege false and misleading conduct by Bayer independent of FDCA violations

Here, preemption is inappropriate because Plaintiffs allege false and misleading conduct by Bayer independent of Bayer's alleged FDCA failures. Bayer cannot bear its heavy burden in establishing that Plaintiffs' state-law claims are preempted, where there is "express pre-emption of cases involving false advertising of dietary supplements in federal law under the FDCA" or any "federal statute or regulation states that the field of allegedly false advertising of dietary supplements is exclusively the province of federal law." *Jackson v. Balanced Health Prods.*, 2009 U.S. Dist. LEXIS 48848, at *8.

Instead, Bayer attempts to argue that Plaintiffs' claims are preempted as an attempt to enforce the FDCA, interfering with the FDA's own enforcement of the FDCA. Def. Br. at 22. However, case law disregarded by Bayer in its opening motion demonstrates that preemption is inappropriate. For example, in *Jackson v. Balanced Health Products*, plaintiffs filed a class action against retailers of dietary supplements alleging that the product "StarCaps," promoted as an "all natural" over the counter diet pill, was "safe, fast and effective." *Id.* at *3. However, StarCaps contained the diuretic compound Bumetanide, which is available only by prescription. *Id.* at *3 n.2. Like Bayer here, the defendants in *Jackson* argued the plaintiffs' complaint was

essentially an assertion that the FDCA was being violated. *Id.* at *9-10 (internal citations omitted). However, the *Jackson* court recognized that "'to the extent that Plaintiffs have alleged that Defendants made statements that were fraudulent (*i.e.*, literally false, misleading, or omitted material facts), their claims are actionable.'" *Id.* at *11 (quoting *In re Epogen & Aranesp Off-Label Mktg. & Sales Practs. Litig.*, 590 F. Supp. 2d 1282, 1290 (C.D. Cal. 2008)). *See also Perez v. Nidek Co.*, 2009 U.S. Dist. LEXIS 78214, at *20 (S.D. Cal. Aug. 31, 2009) (cited by Bayer and recognizing that claims for false or misleading statements remain actionable claims). Given that the plaintiffs' claims were "based on false and misleading advertising," the court rejected the defendants' preemption arguments. *Id.* at *12.

Similarly, Plaintiffs' allegations "do not invoke federal pre-emption," *see id.*, where the Complaint is based on Bayer's false and misleading marketing and advertising of its Products. Plaintiffs allege that Bayer's sale and promotion of products that combine dietary supplements with an over-the-counter drug was false and misleading. Here, Plaintiffs contend Bayer touted its products as having "been proven safe and effective for their marketed purposes," but allege that Bayer deceived consumers regarding the duration for which the products could be safely used, that Bayer preyed on customers' fears and that Bayer sold its products for which no putative benefit would likely be obtained by a consumer. *See, e.g.*, ¶¶ 5, 34, 51, 60, 67. Such allegations are not "based on" and can exist independently of the FDCA. *See* Def. Br. at 22.

Indeed, an important allegation in the Complaint reveals that Bayer promoted its Products as part of a one-a-day aspirin regimen, even though the marketed benefits of Bayer's products could never be obtained under such a regimen. The Complaint alleges that "added ingredients in each medicine [*i.e.*, calcium and phytosterols,] help fight specific diseases long term." ¶ 3. *See also* ¶¶ 37-38, 67. Yet, if Plaintiffs and the members of the Class increased the number of pills

taken daily to avail themselves of the benefits of Bayer's supplements, they face the heightened risk of serious side effects such as gastrointestinal bleeding. ¶ 4. Nevertheless, Bayer marketed Bayer Calcium and Bayer Heart Advantage as safe and effective in mitigating, treating, or preventing osteoporosis and hypercholesterolemia respectively. ¶¶ 39, 67.

Even though Plaintiffs' FDCA-independent allegations call for the rejection of Defendant's preemption arguments,[37] Bayer's FDCA violations can nevertheless be used to support Plaintiffs' state-law claims. For example, such conduct can have evidentiary value or can be used to rebut other of Bayer's arguments. *See, e.g., George v. Ford Motor Co.*, 2007 U.S. Dist. LEXIS 61453, at *21 (S.D.N.Y. Aug. 16, 2007) (denying a defendant's motion to preclude evidence of an automobile manufacturer's withholding of information from a federal agency, grounded in *Buckman,* where the plaintiffs did "not seek in any way to create liability for misstatements to a federal agency" but instead "seek solely to make evidentiary use of such alleged misstatements, to establish elements of traditional state tort claims, or to refute evidence relied upon by defendant."). Notably, one of the cases presently relied upon by Bayer also illustrates this point, namely *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769 (D. Minn. 2009). *See also* Def. Br. at 19. Although *Riley* is factually distinguishable because it involved a medical device subject to an express preemption provision, the *Riley* court rejected a defendant's argument that "a plaintiff can never bring a state-law claim based on conduct that violates the FDCA." *Id.* at 777. Citing *Buckman* and *Riegel v. Medtronic,* 552 U.S. 312 (2009), the court explained that a plaintiff is not prohibited from suing "for conduct that *violates* the FDCA," so

[37] Bayer also argues that the warning letters issued by the FDA are "non-final" agency actions. *See, e.g.,* Def. Br. at 21. However, where this case involves freestanding allegations independent of the FDCA, Bayer's reliance on cases such as *Perez* and *Genendo Pharm. N.V. v. Thompson,* 308 F. Supp. 2d 881 (N.D. Ill. 2003), should not sway this Court.

long as he or she is not suing "*because* the conduct violates the FDCA." *Riley,* 625 F. Supp. 2d at 777 (emphasis in original). Thus, preemption is plainly inappropriate.

2. Given the totality of facts and allegations before this Court, Bayer's reliance on the Supreme Court's decision in *Buckman* is misplaced

Given the totality of the facts and allegations in this matter, Bayer's attempt to draw a parallel between this case and *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341 (2001), fails. Unlike in *Buckman*, Plaintiffs do not seek a remedy for a fraud committed on the FDA or for other violations of the FDCA. Rather, Plaintiffs seek to remedy the consumer fraud and deceptive practices that resulted in the injuries suffered by Plaintiffs and the Class.

In *Buckman*, the plaintiffs sued a consultant retained by a manufacturer of orthopedic bone screws to assist in the FDA-approval process. *Id.* The consultant allegedly made fraudulent statements to the FDA during the course of obtaining marketing approval for the screws on behalf of the manufacturer. 531 U.S. at 343. At issue before the Court was whether the plaintiffs could assert state-law claims against the consultant, where the plaintiffs' fraud allegations existed "solely by virtue of the FDCA disclosure requirements." *Id.* at 353. In finding the plaintiffs' claims preempted, the Court concluded that "were plaintiffs to maintain their fraud-on-the agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments" at issue. *Id.* at 352-53. Instead, the Court found that the plaintiffs' private attempt to enforce a fraud on the FDA conflicted with the FDA's ability to self-police such frauds under the statutory scheme before the Supreme Court. *Id.* at 348-49, 350.

Plaintiffs' case herein is plainly distinguishable. First, factually speaking, Plaintiffs bring state- law claims seeking to remedy the damage caused by Bayer's misrepresentations made directly through its advertisements to the Class, not damage caused by statements by Bayer to the

FDA that constituted a fraud on the FDA.[38] While the *Buckman* court noted that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,'" *Buckman*, 531 U.S. at 347 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)), where Plaintiffs' claims arise under consumer protection law, misrepresentation, and warranty law, the states' historic police powers *are* implicated. *See, e.g., Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 144 (1963) ("Laws regulating the proper marketing of food, including prevention of deceptive sales practices, are within states' historic police powers."); *Automobile Importers of Am., Inc. v. Minnesota*, 871 F.2d 717, 720 (8th Cir. 1989) (correctly recognizing "consumer protection through warranty law" as an "area traditionally regulated by the states").

Thus, in the situation before the Court, Plaintiffs' claims "are premised on traditional duties between a product manufacturer[/marketer]" and consumers and do not "derive from, or [are] based on a newly-concocted duty between a manufacturer and a federal agency." *See Desiano v. Warner-Lambert,* 467 F.3d 85, 94-95 (2d Cir. 2006) (analyzing *Buckman*, 531 U.S. at 352), *aff'd*, 552 U.S. 440 (2008).[39] To conclude that Plaintiffs' claims are preempted would be tantamount to "holding that Congress, without any explicit expression of intent, should nonetheless be taken to have modified (and, in effect, gutted) traditional state law duties between pharmaceutical companies and their consumers." *Id.* at 95. Such a conclusion is plainly inappropriate.

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[38] Indeed, there can be no question that this is not a fraud-on-the-FDA case where Bayer never submitted its products to the FDA for approval in the first place. *See, e.g.*, ¶ 22.

[39] While Bayer attempts to factually distinguish *Desiano*, relying on allegations of physical injury, the Second Circuit's *Buckman* analysis therein is nevertheless controlling and instructive in this case. Again, Bayer attempts to claim that the matter before this Court is one where the "entire claim" is "based on an alleged failure to comply with a federal regulatory scheme." Def. Br. at 21. And again, Bayer's construction is incorrect.

Third, Plaintiffs in fact allege wrongdoing by Bayer unrelated to the alleged FDCA violations. As explained by the Second Circuit in *Desiano*, the Court in *Buckman* suggested that "proof of fraud against the FDA is *alone sufficient* to impose liability," as "[i]n *Buckman* there were no freestanding allegations of wrongdoing apart from the defendant's purported failure to comply with FDA disclosure requirements." *Desiano,* 467 F.3d at 95 (emphasis in original).[40] However, such freestanding allegations exist, as exemplified by Plaintiffs' allegations related to Bayer's sale and marketing of its products for which no putative benefit would likely be obtained by a consumer. Thus, preemption is inappropriate here.

3. *Wyeth v. Levine* also calls for the denial of Bayer's preemption arguments

Third, Bayer argues that preemption is appropriate because the FDA "is empowered to *balance* competing statutory objectives related to its own approval procedures," contending that flexibility is needed in order for the FDA to pursue its statutory objectives. Def. Br. at 20 (emphasis added). Bayer contends that Plaintiffs' claims would serve to interfere with this balance, positing that the Supreme Court's decision in *Wyeth v. Levine,* __ U.S. __, 129 S. Ct. 1187 (2009), is inapplicable, even though the Court rejected a similar preemption argument.

This Court should reject Bayer's weak attempt to distinguish *Wyeth* based on its personal injury facts.[41] *See* Def. Br. at 21. In *Wyeth,* the defendant drug company argued that the FDA-

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[40] Because Plaintiffs' Complaint contains allegations that establish Bayer's wrongdoing independently of Bayer's alleged FDCA violations, two cases on which Bayer relies are distinguishable. First, in *Perez v. Nidek,* 2009 U.S. Dist. LEXIS 78214, at *1, the district court found plaintiffs' state-law claims were preempted where they only "rest[ed] upon" allegations of violations of the FDCA and where they would "require the Court to make determinations" that "should be decided by the FDA in the first instance." *Id.* at *20-21. Like the Second Circuit in *Desiano,* however, the *Perez* court explained that "not all claims that touch upon subject matter regulated by the FDCA are preempted," pointing to "literally false or misleading statements made to promote drugs or devices" as one actionable example. *Id.* at *20. Similarly, Bayer relies upon *Anthony v. Country Life Mfg., LLC*, 2002 U.S. Dist. LEXIS 19445, at *1 (N.D. Ill. Oct. 7, 2002), distinguished at pages 16-17, *supra.*

[41] Bayer ignores the recent consumer fraud cases that apply *Wyeth. See, e.g., Holk v. Snapple Bev. Corp.*, 575 F.3d 329, 335 (3d Cir. 2009) (applying preemption discussion explained in *Wyeth*, in a consumer fraud action alleging marketed "All Natural" products were not in fact natural, and reversing district court's preemption dismissal); *In re Hollis*, 2009 Bankr. LEXIS 3020, at *26-27 (Bankr. D.N.J. Sept. 17, 2009) (citing *Wyeth* and

approval process provided it with a complete defense to the plaintiff's state-law claims. 129 S. Ct. at 1191. Wyeth argued that preemption of the plaintiff's state-law claims was necessary because such claims "interfere[d] with Congress's purpose to entrust an expert agency to make drug labeling decisions that strike a *balance* between competing objectives." *Id.* at 1199 (emphasis added and internal quotation omitted). However, the Supreme Court found "no merit in this argument" as it relied "on an untenable interpretation of congressional intent and an overbroad view of an agency's power to preempt state law." *Id.*

In breaking down Wyeth's "balance" argument, the Court explained that Congress did not enact an express preemption provision in the FDCA as it related to drugs, though it did so with respect to medical devices. *Id.* at 1200. The Court noted that Congress likely "recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." *Id.* at 1199-1200. Thus, Congress's silence on the issue, "coupled with its certain awareness of the prevalence of state tort litigation, [was] powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 1200.

Finding that "Congress did not regard state tort litigation as an obstacle to achieving its purposes," the Court struck down the same "balancing" argument Bayer makes here. *Id.* at 1200 (citing 71 Fed. Reg. 3922 (2006)). Recognizing the FDA's limited resources, the Court explained that the "FDA traditionally regarded state law as a complimentary form of drug regulation," consistent with "Congress' decision not to pre-empt common-law tort suits." *Id.* at 1202.

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rejecting Truth in Lending Act-related preemption arguments offered by a defendant in connection with a bankruptcy proceeding alleging consumer fraud arising out of a mortgage transaction).

The Supreme Court's analysis is directly applicable here. First, like in *Wyeth*, the present case concerns the impact of the FDCA on state law causes of action. Second, just as no express preemption provision applied in *Wyeth,* no express preemption provision is at play here. Third, just as the *Wyeth* Court noted that state law failure to warn claims furthered "consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings," the state-law remedies at issue here similarly serve to motivate manufacturers – to truthfully and accurately represent the nature of their products. Fourth, like Wyeth, Bayer has argued that state law interferes with federal law where the FDA is "empowered to balance competition statutory objectives," but (again like Wyeth) points to no statement of Congress. Finally, just as the *Wyeth* Court had "no occasion…to consider the pre-emptive effect of a specific agency regulation bearing the force of law," this Court does not either where Bayer "relied on the preexisting regulatory review of aspirin and the supplements" and did not submit a New Drug Application for each of the products. *See* Def. Br. at 1. Thus, just as the Supreme Court rejected Wyeth's "balancing" argument, this Court should do the same.

IV. CONCLUSION

WHEREFORE, Plaintiffs respectfully request that the Court (1) deny Defendant's motion to dismiss in its entirety; (2) in the alternative, grant Plaintiffs' request for leave to amend the Master Complaint; and (3) grant such other and further relief as is just and proper under the circumstances.

Dated: New York, New York
November 5, 2009

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